in Hind "for the relief of pain" in patients with "post-herpetic neuralgia" would somehow inherently involve treating "neuropathically-induced sensory phenomena" or "numbness" to restore sensation with the anesthetic compositions recited in the claims.

Inherent anticipation requires an element that is not expressly recited in a reference to be "necessarily present" and this "would be so recognized by persons of ordinary skill." (MPEP 2131.01 at part III; Continental Can Co. USA v. Monsanto Co., 948 F.2d 1264 (Fed. Cir. 1991).) Stated differently, inherency may not be established by mere probabilities or possibilities. In re Robertson, 169 F.3d 743 (Fed. Cir. 1999). Additionally, the Patent Office has the burden of providing "a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art." Ex Parte Levy, 17 USPTO 2d 1461 (Bd. Pat. App. & Inter. 1990) (emphasis added). The Applicants respectfully submit that the rejection fails to satisfy this burden or otherwise establish inherent anticipation.

This is because "negative sensory phenomena" or "numbness" are separate symptoms and may be entirely absent in patients suffering from "post-herpetic neuralgia." Thus, "negative sensory phenomena" or "numbness" are not "necessarily present" in patients suffering from "post-herpetic neuralgia" despite the contrary assumption of the rejection.

The art accepted definitions of "neuralgia" and "post-herpetic neuralgia" as well as other teachings in the literature relating to "post-herpetic neuralgia" render this quite apparent.

"Neuralgia" is defined as "acute paroxysomal pain radiating along the course of one or more nerves … [usually] without demonstrable changes in the nerve structure" or as "[p]ain of a severe, throbbing, or stabbing character in the course or distribution of a nerve…[etymology=] [neur- + G. *algos*, pain]" in Stedman's Medical Dictionary, 28th Edition, 1307 (28th Ed. 2006) (emphasis added), *see also* Merriam Webster's Medical Desk Dictionary, 471 (1993) (emphasis added). Stated differently, "neuralgia" is a type of pain—not a type of "negative sensory phenomena" or "numbness."

Moreover, "post-herpetic neuralgia" or "PHN" is defined as "causalgia [(burning pain)] and hyperesthesia [(excessive, painful sensitivity to sensory stimuli)] in the dermatome served by a spinal nerve infected by herpes zoster, persisting after resolution of the skin eruption; typically occurs in middle-aged and old people [(and)]; may continue for weeks, months or years" in Stedman's Medical

Dictionary, 28th Edition, 1307 (28th Ed. 2006). Stated differently "post-herpetic neuralgia" is a type of pain following herpes zoster infection—not a type of "negative sensory phenomena" or "numbness."

It is also apparent from a brief review of the medical literature that "negative sensory phenomena" or "numbness" are not "necessarily present" in patients presenting with "post-herpetic neuralgia." This is can be seen from the disclosure in Hasnie as well as Rowbotham. For example, Hasnie states on page 8:

> In established postherpetic neuralgia the clinical phenotype varies between individual patients and possibly over the time course of the disease. A spectrum of abnormal sensory phenomena have been documented, with hyper-sensory phenomena, such as allodynia [(pain elicited by ordinarily non-painful stimuli)] and hyperalgesia [(increased sensitivity to pain or enhanced sensitivity to pain)], at one extreme and a predominantly hyposensory picture [(a deficient response to stimuli)] with pain in the context of partial or complete sensory loss at the other.

Thus, Hasnie teaches that post-herpetic neuralgia can occur without "negative sensory phenomena" or "numbness" and patients with post-herpetic neuralgia can have only painful symptoms.

This is also apparent from Rowbotham. For example, Rowbotham states at page 348:

> In a previous study of PHN [(post-herpetic neuralgia)] patients (1989), we were struck by how many patients with severe pain had little, if any sensory deficit in the region they felt was the source of their most severe pain.

Moreover, Rowbotham presents clinical data in Fig. 3 showing that patients can have "post-herpetic neuralgia" without any sensory deficits, such as thermal sensory deficits. Thus, Rowbotham also teaches, and demonstrates in the clinic, that post-herpetic neuralgia can occur without "negative sensory phenomena" or "numbness" and patients with post-herpetic neuralgia can have only painful symptoms.

It is further apparent that Medline relied on in the rejection to show inherency is deficient. In particular, Medline incorrectly states that a symptom of "neuralgia" is "numbness of the affected skin area (feeling similar to a local anesthetic, such as a Novocain shot)." This error is proven from the

above definitions of "neuralgia" provided by art accepted authorities. The painful symptoms of neuralgia such as "acute paroxysomal pain," "pain of a severe, throbbing or stabbing character" and burning pain such as in "causalgia" are nothing like "numbness" and are, in fact, quite the opposite of the sensations one associates with receiving a shot of the local anesthetic NOVOCAIN™. Moreover, the Applicants respectfully submit that the presence of such errors in Medline is one reason why the Medline reference contains an explicit disclaimer which states on page 3:

> The information provided should not be used during any medical emergency or for the diagnosis or treatment of any medical condition. A licensed physician should be consulted for diagnosis and treatment of any an all medical conditions. Call 911 for all medical emergencies. Adam makes no representation or warranty regarding the accuracy, reliability, completeness, currentness, or timeliness of the content, text or graphics. (Emphasis added.)

In contrast, Hasnie and Rowbotham are articles written by medical and scientific professionals and published in respected, peer-reviewed medical journals, whose conclusions are based on actual clinical results presented in the articles. Thus, the Applicants respectfully submit that the advice in the Medline disclaimer should be followed and this document should not be relied on—particularly to support the current inherent anticipation based rejections—as it contains erroneous information as demonstrated by other reliable sources.

It is also apparent from the literature that the pain of "post-herpetic neuralgia" can occur without "negative sensory phenomena" or "numbness" and patients with post-herpetic neuralgia can have only painful symptoms. This means that Hind does not inherently disclose treatment of "negative sensory phenomena" or "numbness" because patients with "post-herpetic neuralgia" do not necessarily have symptoms of "negative sensory phenomena" or "numbness." In fact, Hind in column 1, lines 28-30 acknowledges this when it states that "PHN patients nearly always have a sensory deficit in the region obtained." (Emphasis added.) Importantly, "nearly" having a symptom is nothing like a symptom "necessarily being present." Hind also does not disclose that patients treated with the disclosed methods exhibit any symptom other than "pain" from "post-herpetic neuralgia" Thus, it is inappropriate to infer, based on the erroneous disclosure of the Medline reference, and contrary to the teachings in the accepted, peer-reviewed medical literature, that these patients present any symptom other than pain from "post-herpetic neuralgia."

Hence, Hind is silent regarding the treatment of "negative sensory phenomena" or "numbness" with the anesthetic compositions of Claims 1-11 and contriving to cure this deficiency by reliance on Medline and/or Rowbotham is improper. Moreover, the Applicants have factually established that "negative sensory phenomena" or "numbness" might be present, but surely is not "necessarily" present, and accordingly is anything but inherent in patients suffering from PHN.

Altogether, the above discussion makes it clear the inherent anticipation based rejection of Claims 1-11 over Hind as evidenced by Medline and Rowbotham should be withdrawn.

Claims 1-11 are also not anticipated because all three references fail to disclose all the elements of the claims. Independent Claim 1 recites the steps of "a) identifying a patient with neuropathically-induced negative sensory phenomena; b) identifying a locus of the neuropathically-induced negative sensory phenomena; and c) applying an anesthetic topically to the skin of the patient with neuropathic negative sensory phenomena at or near the locus of the negative sensory phenomena; whereby the neuropathically-induced negative sensory phenomena in the patient is treated." Independent Claim 9 recites the steps of "a) identifying a patient with neuropathically-induced negative sensory phenomena; b) identifying a locus of the neuropathically-induced negative sensory phenomena; and c) applying a non-woven polyester cloth including a physiologically acceptable adhesive, comprising from about 2 to 10% by weight of lidocaine, to the skin of a patient at or near the locus of the negative sensory phenomena; whereby the neuropathically-induced negative sensory phenomena in the patient is treated." Independent Claim 11 recites the steps of "a) identifying a patient with numbness of the skin; b) identifying a site of the numbness of the skin; and c) topically applying a local anesthetic to said skin at, or near, the site of said numbness; whereby the numbness of the skin of the patient is decreased." Importantly, Hind fails to teach these steps of the claimed methods and Medline/Rowbotham fail to show these steps are necessarily inherently present in the disclosure of Hind. This means there can be no anticipation, or inherent anticipation, under 35 USC §102(b) of Claims 1-11 by Hind as evidenced by Medline and Rowbotham. The Applicants respectfully request withdrawal of the rejection of Claims 1-11 as inherently anticipated under 35 USC §102(b).

Claims 1-11 are rejected as obvious under 35 USC §103(a) over Hind, Medline in view of Wolicki. Claims 1-11 are not obvious over Hind in view of Wolicki as evidenced by Medline and Rowbotham. Reasons are set forth below.

First, Hind, Medline and Rowbotham represent the core combination of references relied on to support the obviousness rejections. However, Medline is not prior art under 35 USC §102 and is not available for application in the obviousness rejection made under 35 USC §103(a). Thus, the rejection fails on this basis to establish *prima facie* obviousness.

Second, the obviousness rejection improperly relies on the doctrine of inherent anticipation. This is apparent from the comments in the rejection regarding "incorporation" of the inherent anticipation arguments relating to Hind, Medline and Rowbotham into this obviousness rejection. However, the doctrine of inherent anticipation cannot properly be applied in the context of 35 USC §103 an obviousness rejection. This means the rejection incorrectly relies on arguments which conflate anticipation and anticipation related doctrines with obviousness and obviousness related doctrines. Such conflation is prohibited because the case law, such as Atlas Powder Co. v. Ireco Inc. (190 F.3d 1342 (Fed. Cir. 1999)), teaches that the application of the inherent anticipation doctrine is limited to the context of 35 USC §102 anticipation not obviousness under 35 USC §103. Moreover, it is self evident to state:

> That which may be inherent is not necessarily known. Obviousness cannot be predicated on what is unknown. In re Spormann and Heinke, 150 USPQ 499, 452 (CCPA 1996) (emphasis added).

Hence, application of the inherency doctrine is limited to anticipation based rejections made under USC §102. Thus, the obviousness rejection is inappropriate on these bases and should be withdrawn as the rejection fails to establish *prima facie* obviousness.

Third, Claims 1-11 are not obvious because the combination of Wolicki with Hind as evidenced by Medline and Rowbotham fails to disclose all the elements of the claims. This is because, as discussed above, the core combination of Hind, Medline and Rowbotham fails to teach all the elements of Claims 1-11 while Wolicki does nothing to cure this deficiency of the core combination of references. Moreover, the combination of Wolicki with Hind also fails to teach all the elements of Claims 1-11. This is important because, as discussed above, Medline is not available as prior art for application in this obviousness rejection. Thus, the rejection also fails on these bases to establish *prima facie* obviousness.

Fourth, Claims 1-11 are not obvious because one of ordinary skill in the art would not be motivated to perform the claimed methods, or reasonably expect success on so doing. This is

because nothing in the cited references suggests that a topically applied anesthetic (*i.e.*, a compound known to block sensation) can cause sensation to return or improve tactile response and sensory loss in patients with neuropathically-induced "negative sensory phenomena" or "numbness" of the skin. Importantly, the Applicants have defied the teachings in the art and unexpectedly found that a topically applied anesthetic could treat the conditions of neuropathically-induced "negative sensory phenomena" or "numbness" of the skin in patients. The Applicants respectfully submit this compelling evidence of non-obviousness. Thus, the rejection also fails on these bases to establish *prima facie* obviousness.

The Applicants respectfully request withdrawal of the rejection of Claims 1-11 as obvious under 35 USC §103(a).

In light of the foregoing, the Applicants respectfully submit that the entire application is now in condition for allowance, which is respectfully requested.

Respectfully submitted,

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